The drawings have been objected to as failing to comply with 37 CFR 1.84(p)(5). The Office states that "they do not include the following reference sign(s) mentioned in the description: elements (82) and (244)". As requested by the Office, Applicants have amended the drawings and specification.

2. 35 U.S.C. §102 Rejections

Claims 1-6, 7-25, 33 and 34-36 have been rejected under 35 U.S.C. §102(b) as being anticipated by Anderson (795). The Office states:

> Anderson (795) discloses a method and apparatus showing the positioning of the body portion (umbilical cord) within a curved shield member (21) of medical grade material (Co. 4, lns. 51-55), and inserting an insertion member into the umbilical cord to extract blood (Col. 5, lns. 21-67) in the form of a hollow needle (73). Regarding claim 11, the withdrawal step and the removing the body portion of obvious steps that the physician would take to complete the process.

Applicants respectfully traverse this rejection.

The Anderson reference describes a complex apparatus and method for withdrawal of placental blood from an umbilical cord vein. According to Anderson, the apparatus includes a number of valves, ports, channels, needles, tubes and clamps. In particular, the Anderson apparatus includes a valve 1 with a housing 2 that has a central cavity 3 and a single open end 50. The housing 2 further has a first channel 4 that has an outer port 4a and an inner port 4b, a second channel 5 that has an outer port 5a and an inner port 5b, a third channel 6 that has an outer port 6a and an inner port 6b, and a fourth channel 7 that has an outer port 7a and an inner port 7b. Outer ports 4a, 5a, 6a, and 7a all have threads capable of receiving mating threads or flanges that are located on syringes, one-way valves, needles, or an orifice on a blood storage bag. A one-way valve 51 is connected between outer port 4a and butterfly-type needle 60. The butterfly-type needle 60 includes a hollow needle 73, a first flange 72, and a second flange 74. The first flange 72 and second flange 74 are operatively connected to oppositely disposed sides of needle 70. A second one-way valve 52 is connected between outer port 5a and storage bag 62, which is for storing a blood and

anticoagulant mixture. A rotatable disk 8 is located within cavity 3. Disk 8 has a fifth channel 9 that has a T configuration and three ports 9a, 9b, and 9c. The fifth channel 9 is oriented in the disk 8 so that when the disk 8 is in a first position, port 9a mates with inner port 4b, port 9b mates with inner port 5b, and port 9c mates with inner port 6b. Disk 8 also includes sixth channel 10 that has two ports 10a and 10b. When the disk is in a second position, sixth channel 10 is oriented so that ports 10a and 10b mate with inner ports 7b and 6b, respectively, and ports 9a, 9b, and 9c are disengaged from inner ports 4b, 5b, and 6b. Disk 8 has a shaft 11 that extends from the top of the disk 8 along its axis. Handle 14 is attached to shaft 11 by screw so that the disk 8 rotates as handle 14 is moved from one position to another. A blood collection syringe 53 is attached to outer port 6a and an anticoagulant syringe 54 is attached to outer port 7a. An umbilical cord holder 20 having a curved trough 21 that has an open top 22, a flange 23 extending downward from the first end of the trough 21 and a stem 36 extending downward from trough 21. At one end of the trough is a cut-end umbilical cord clamp 26 having clamping portions 27a and 27b and at the opposite end of the trough is an identical clamping mechanism. The stem 36 is located at a distance from cut-end umbilical clamp 26 and flange 23 sufficient to allow a person to insert their little finger between flange 23 and stem 36. (See col. 3 line 36 – col. 5, line 20 and Figs. 1-6)

In order to collect placental blood a complex procedure is followed. As set out by Anderson, the umbilical cord holder 20 is placed in a first hand such that the stem 36 is located between the little and fourth fingers. The curved trough 21 lays along the base of the fingers and adjacent to the palm. The umbilical cord 68 is then placed in trough 21 so that the umbilical cord 68 extends from the placenta through uncut-end umbilical cord clamp 32, the trough 21, and the cut-end clamp 26. The cut-end clamp 26 restricts the umbilical cord. After the hollow needle 73 is inserted into the umbilical vein, either the first flange 72 or the second flange 74 is placed against one edge of the trough 21. The user can then rest his/her thumb on top of the flange 72 or 74 and hold the hollow needle 73 in axial alignment with the umbilical vein. This operation is important because a movement in the user's first had 67 would otherwise cause the hollow needle 73 move out of axial alignment with the umbilical vein and

restrict the flow of blood through the hollow needle 73. After hollow needle 73 is inserted into the umbilical cord, valve 1 is set in the first hand 67 so that it is gripped between the base of the palm and the finger tips. Holding valve 1 and the umbilical cord holder 20 in this manner allows the user to keep his/her second hand, not shown, free to continue surgical procedures. The handle must then be turned to orient the disk 8 in its first position so that port 9a is aligned with inner port 4b, port 9b is aligned with inner port 5b, and port 9c is aligned with inner port 6b. The plunger 69 of the blood collection syringe 53 is then withdrawn thereby causing blood to flow from the placenta through a vein in the umbilical cord, the needle 60, the one-way valve 51, the first channel 4, the fifth channel 9, the third channel 6, and into the blood collection syringe 53. (See col. 5, lines 21-62) Further steps can then be taken to mix anticoagulant with the blood and store the mixture in storage bag 62.

Applicants, on the other hand, teach a device and method for the collection of blood. Applicants' device is simple in construction and is inexpensive to manufacture. Further, the use of Applicants' device is simple and does not involve highly detailed procedures or complex methods embodying multiple steps.

In particular, Applicants' methods for collecting umbilical cord blood include positioning an umbilical cord within a shield member, stabilizing the umbilical cord using a digit of the user's hand and contacting the cord with a blood extraction device. (See claim 19) Likewise, claim 1 claims methods for collecting blood comprising positioning a body portion, from which blood is to be withdrawn, within a shield member such that the shield member is generally disposed between the body portion and a hand of a user, stabilizing the body portion using a digit of the user's hand, and inserting an insertion member of a blood extraction device into the body portion such that the shield member is generally disposed between the insertion member and the user's hand. (See claim 1) Claim 34 claims a similar method for the collection of blood from an umbilical cord comprising providing a shield member, holding the shield member with one hand of a user, positioning the umbilical cord within the shield member such that the shield member is generally disposed between the umbilical cord and the one hand, stabilizing the umbilical cord using a digit of the

user's hand while holding the shield member using the one hand, inserting an insertion member of a blood extraction device into the umbilical cord using another hand of the user such that the shield member is generally disposed between the insertion member and the one hand, and withdrawing the cord blood from the umbilical using the blood extraction device. (See claim 34)

Applicants also teach a shielding device comprising a cradle member, the cradle member being configured so one portion thereof is releasably held in a hand of a user, so another portion thereof releasably receives the body portion, and so a digit of the user's hand secures the body portion in the another portion while holding the cradle member. (See claims 19 and 36) According to claim 36, said another portion includes a surface recess extending along an axis of the cradle member, in which recess is received the body portion the recess and said one portion are configured so as to be arcuate in cross-section. (See claim 36) Similarly, Applicants teach an apparatus for extracting cord blood from an umbilical cord comprising a cradle member configured and arranged so one portion thereof is releasably held in a hand of a user, so another portion thereof releasably receives the umbilical cord, and so a digit of the user's hand secures and stabilizes the umbilical cord in said another portion while holding the cradle member, and a blood extraction device including an insertion member being configured so as to inserted into the umbilical cord and to withdraw cord blood therefrom. (See claim 25)

The Anderson reference does not describe or otherwise suggest a method or apparatus for collecting blood wherein a body portion, from which blood is to be withdrawn, within a shield member such that the shield member is generally disposed between the body portion and a hand of a user, stabilizing the body portion using a digit of the user's hand, and inserting an insertion member of a blood extraction device into the body portion such that the shield member is generally disposed between the insertion member and the user's hand. Rather, the Anderson reference describes a complex apparatus including a number of valves, ports, channels, needles, tubes and clamps. According to Anderson, the umbilical cord is placed in the device such that the umbilical cord extends from the placenta through uncut-end umbilical

cord clamp and to the cut-end clamp. These clamps are squeezed together so that the male and female portions of the clamps secure together to restrict the umbilical cord.

As provided in MPEP-2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suziki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

Applicants respectfully submit that the Anderson reference does not describe each and every element as set forth in claim 1. In particular, the Anderson reference does not describe or otherwise suggest stabilizing the body portion (umbilical cord) using a digit of the user's hand.

Further, Applicants respectfully submit that there is no suggestion or motivation to modify Anderson as required by Applicants' claim 1 to stabilize the body portion using the digit of the user's hand. Rather, according to the Anderson reference, the digits of the user's hand are used for other purposes. The umbilical cord holder 20 is placed in a first hand such that the stem is located between the little and fourth fingers and the curved trough 21 lays along the base of the fingers and adjacent to the palm. (See col. 5, lines 21-25) After the hollow needle 73 is inserted into the umbilical vein, the user can rests his/her thumb on top of the flange 72 or 74 and hold the hollow needle 73 in axial alignment with the umbilical vein. This operation is important because a movement in the user's first had 67 would otherwise cause the hollow needle 73 move out of axial alignment with the umbilical vein and restrict the flow of blood through the hollow needle 73. (See col. 5, lines 39-47) The user then turns the handle 14 to orient the disk 8 in its first position so that port 9a is aligned with inner port 4b, port 9b is aligned with inner port 5b, and port 9c is aligned with inner port 6b. The user then withdraws the plunger 69 of the blood collection

syringe 53 thereby causing blood to flow from the placenta through a vein in the umbilical cord, the needle 60, the one-way valve 51, the first channel 4, the fifth channel 9, the third channel 6, and into the blood collection syringe 53. The user then turns the handle 14 to orient the disk 8 in its second position, etc. (See col. 5, lines 55-66)

Applicants respectfully submit that if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)

In the present case, modification of the Anderson reference as required by Applicants' claim 1 to stabilize the body portion using the digit of the user's hand, would render Anderson unsatisfactory for its intended purpose. If one were to use the Anderson device in such a way so as to stabilize the body member (umbilical cord) with the digit of the user's hand, then the various steps required to use the Anderson device, e.g. holding the hollow needle 73 in axial alignment with the umbilical vein, turning handle 14 to orient the disk 8 in its various position positions, withdrawing plunger 69 of the blood collection syringe 53, could not be carried out as intended.

Accordingly, claims 1, 16, 19, 25, 34 and 36 are patentable over the Anderson reference. Claims 2-15 and 33 depend from claim 1 and, likewise, are patentable over the Anderson reference. Claims 17-18 depend from claim 16 and, likewise, are patentable over the Anderson reference. Claims 20-24 depend from claim 19 and, likewise, are patentable over the Anderson reference. Claim 35 depends from claim 34 and, likewise, is patentable over the Anderson reference

3. 35 U.S.C. §103 Rejections

Claims 26-32 and 37 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson (795) in view of Gleason. The Office states:

Anderson (795) discloses the limitations above but do not disclose the use of the device with a kit.

> Gleason discloses the use of a blood collection/sampling device in a kit in an analogous art for the purpose of having ready access to all the necessary devices to perform the operation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Anderson (795) as shown by Gleason because the inclusion of the device in a kit would make the device more useful when it would be needed.

Applicants respectfully traverse this rejection for the same reasons as set forth above regarding the Anderson reference. Further, the Gleason reference does not remedy the deficiencies set out above regarding the Anderson reference.

CONCLUSION

Reconsideration and allowance of claims 1, 2 and 5-37 is respectfully requested in view of the foregoing discussion. This case is believed to be in condition for immediate allowance. Applicant respectfully requests early consideration and allowance of the subject application.

Applicants believe that no extension of time is required since this response is being filed before the expiration of the specified time period. Applicants, however, conditionally petition for an extension of time to provide for the possibility that such a petition has been inadvertently overlooked and is required. As provided below charge Deposit Account No. **04-1105** for any required fee.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

Respectfully submitted,

Date: Dec. 10, 2002

Lisa Swiszcz Hazzard (Reg. No. 44,368)
Dike, Bronstein, Roberts & Cushman
Intellectual Property Group of
EDWARDS & ANGELL, LLP
P.O. Box 9169
Boston, MA 02209
Tel. No. (617) 517-5512

#320284

VERSION WITH MARKINGS TO SHOW CHANGES MADE IN CLAIMS

Please note that additions to the claims are shown underlined and deletions are shown in brackets.

1. A method for collection of blood comprising:

positioning a body portion, from which blood is to be withdrawn, within a shield member such that the shield member is generally disposed between the body portion and a hand of a user;

stabilizing the body portion using a digit of the user's hand; and

inserting an insertion member of a blood extraction device into the body portion such that the shield member is generally disposed between the insertion member and the user's hand.

Please cancel claims 3 and 4, without prejudice.

16. A method for collection of umbilical cord blood comprising:

positioning an umbilical cord within a shield member;

stabilizing the umbilical cord using a digit of the user's hand; and

contacting the cord with a blood extraction device.

34. A method for collection of blood from an umbilical cord (cord blood), comprising:

providing a shield member, one portion of which is configured to be releasably held in one hand of a user and another portion of which is configured to releasably receive the umbilical cord, wherein the another portion includes a surface recess extending along an axis of the shield member, in which is received the umbilical cord and wherein the recess and the one portion are each arcuate in cross-section;

holding a shield member with one hand of a user;

positioning the umbilical cord within the shield member such that the shield member is generally disposed between the umbilical cord and the one hand;

stabilizing the umbilical cord using a digit of the user's hand while holding the shield member using the one hand;

inserting an insertion member of a blood extraction device into the umbilical cord using another hand of the user such that the shield member is generally disposed between the insertion member and the one hand; and

withdrawing the cord blood from the umbilical using the blood extraction device[;].

VERSION WITH MARKINGS TO SHOW CHANGES MADE IN SPECIFICATION

Please note that additions to the specification are shown underlined and deletions are shown in brackets.

For the illustrated safety device, by forward directed thumb or finger stroke upon a proximally projecting shaft 130, pushrod 128, [that] which is slidably operable within a pushrod channel [82] slides forward. The pushrod 128 is positioned parallel to and radially removed from the primary syringe barrel plunger 44.[,] As the pushrod slides forward, the elongated shield 148 is pushed from a housing 66 mounted at the base of the hypodermic needle and syringe apparatus 42 and rotated longitudinally from an inverted position. The elongated shield 148 [also] is thus advanced to the distal end of the syringe apparatus 42 against resistance from a rubber band 64 or integral expansion spring, not shown[244]. In one embodiment, for example, as shown in Fig. 4, the rubber band is mounted on a peg 80 projecting from a portion of the housing 66, extends through an aperture in the housing and connects to the shield 148. As the shield is pushed from the housing and rotates longitudinally from its inverted position, [T]the distal portion of the shield 148 surmounts the tip of the needle 54 and the needle 54 enters the shield 148 laterally through an opening in the shield face 154. The operator then releases thumb or finger pressure upon the pushrod 128 and the enclosed forward end of the shield 148 is pulled rearward by the rubber band 64 or integral expansion spring [244] to surround and safely contain the needle 54 tip.

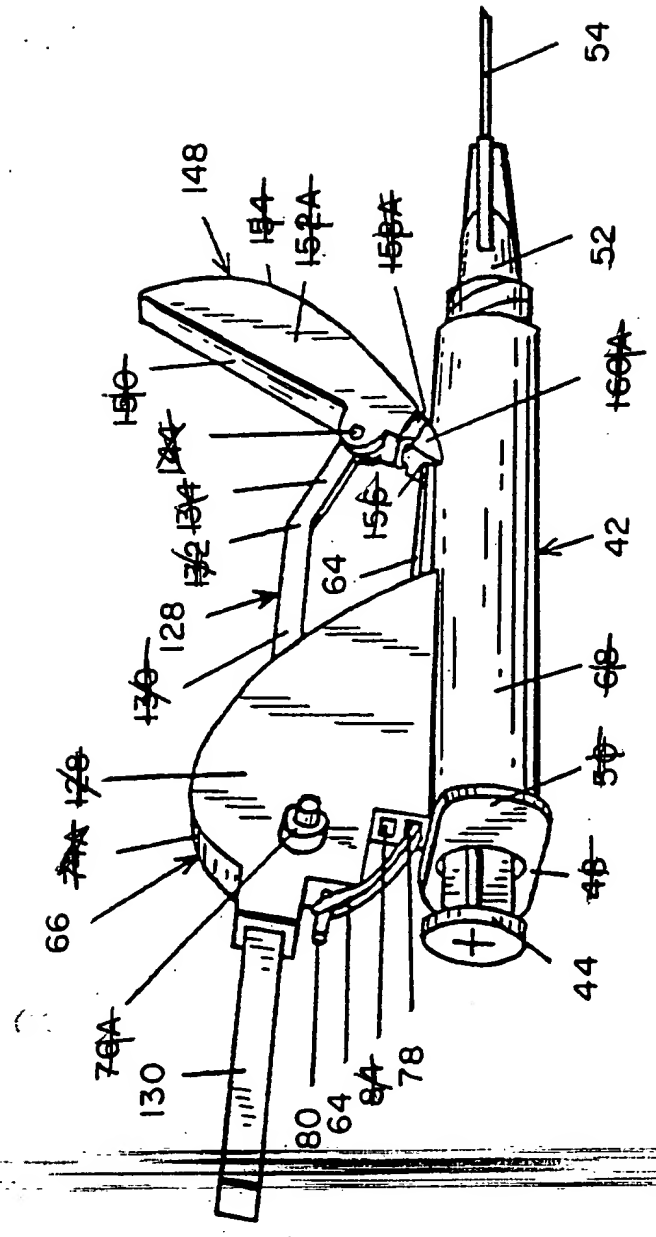

FIG. 4